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(71) Applicant *(for all designated States except US)*: VASCU-LAB LTD. [IL/IL]; 21 King Shaul Boulevard, 64367 Tel Aviv (IL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: BASH, Assaf [IL/IL]; Haseora 1, 37808 Givat Ada (IL). BAR-OR, Jonathan [IL/IL]; Kibbutz Degania A, 15120 Jordan Valley (IL). SHACHAR, Rotem [IL/IL]; Kibbutz Metzer, 38820 Mobile Post Hefer (IL). BEN DAVID, Shlomo [IL/IL]; 19 Yehuda Hanasi Street, 69206 Tel Aviv (IL).

(74) Agent: REINHOLD COHN AND PARTNERS; P.O.Box 4060, 61040 Tel Aviv (IL).

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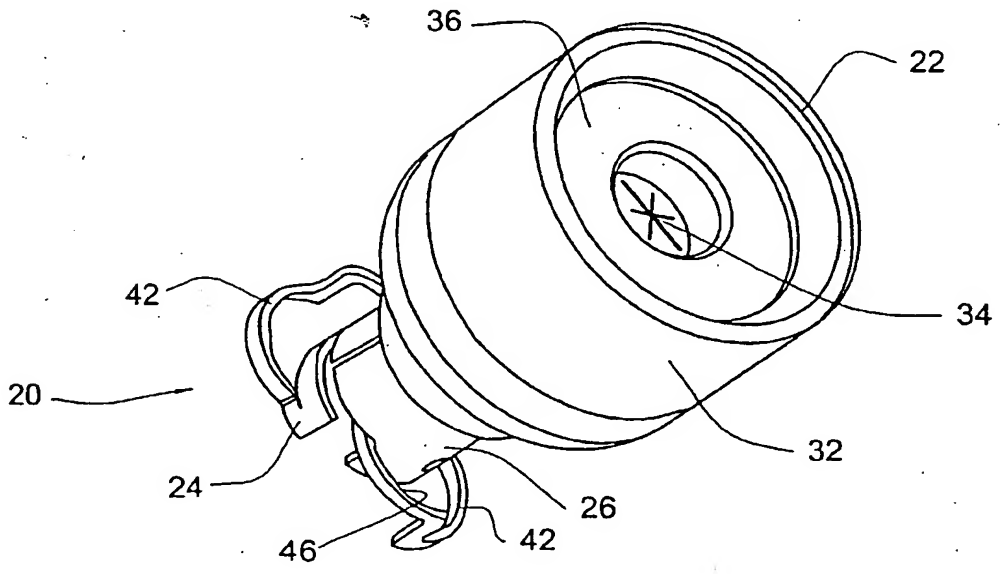
(54) Title: DEVICE AND METHOD FOR SEALING A PUNCTURE IN A BLOOD VESSEL



(57) Abstract: A sealing device for sealing a puncture in a blood vessel, the device being slidingly receivable over a guide tube and comprising a sealing portion, a wall-engaging portion extending between an external bearing member for bearing over an external surface of the blood vessel, and an internal bearing member for bearing against an inner surface of the blood vessel. At least the internal bearing member is manipulable between a constricted position in which it is essentially coextensive with the wall-engaging portion and an expanded position in which it engages the inner surface of the blood vessel.

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DEVICE AND METHOD FOR SEALING A PUNCTURE IN A BLOOD VESSEL

FIELD OF THE INVENTION

The present invention is generally in the field of homeostatic devices and in particular it is directed to a sealing device and a method utilizing same for sealing punctures in any blood vessel of a patient during or after a medical procedure.

BACKGROUND OF THE INVENTION

During several surgical procedures carried out, for example in treatment of vascular diseases, it is common practice to invade a blood vessel and introduce a treating or diagnostic device, e.g. balloons or various types of stents to operate on walls of the arteries, plaque removing devices, observation and flow diagnostic instruments, etc.

During such procedures, a blood vessel is punctured so as to allow introduction of the instrument through the artery and then maneuver it to the required site of operation. This is carried out in practice by introducing a guide tube often referred to as an *"introducer sheath"*, through which the instrument can then be easily maneuvered to the site of interest.

A problem occurs once the procedure is complete and the guide tube has then to be removed, when the percutaneous puncture bleeds. Bleeding may result in hematoma or in severe cases to malfunction of critical organs and even death. Such bleeding is stopped, by a most common method, by simply applying pressure on to the puncture site by a medically trained person for a sufficiently long period of time until homeostasis takes place to spontaneously seal the puncture and stop the bleeding.

In cases of puncturing the femoral arteries, the required time may be as long as about 45 minutes or more and in some cases re-bleeding occurs if the patient is not in rest.

A variety of methods and devices have been suggested for replacing the traditional method disclosed above, some of which involve introducing chemical compounds which act as homeostasis catalysts or as adhering agents, whilst others aim at introducing various forms of plugging members into the puncture. The following is a list of prior art patents disclosing devices and methods for sealing punctured blood vessels: U.S. 4,705,040 4,890,612, 4,929,246, 5,108,420, 5,342,393, 5,350,399, 5,391,183, 5,613,974, 5,810,884, 5,861,003, 5,957,952, 5,984,950, 6,007,563 and WO 98/31287.

It is an object of the present invention to provide a series of novel devices for sealing a puncture or incision formed in a blood vessel or in other body organs.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a sealing device and a method utilizing same, for sealing a puncture or incision formed in a body organ, typically in a blood vessel. A device in accordance with the present invention has the unique advantage of being introduced into the puncture over a guide tube (sheath) and is self adaptable for use in a wide range of sizes of guide tubes. The device is fitted with anchoring means to ensure suitable anchorage within the puncture and is self adapted for a variety of wall thicknesses of the blood vessel at the puncture site.

An advantage of a device according to the present invention is that once it is introduced into the puncture or incision it can be rapidly deployed into its operative sealing position.

According to the present invention there is provided a sealing device for sealing a puncture in a blood vessel, said device being slidingly receivable over a guide tube and comprising a sealing portion, a wall-engaging portion extending between an external bearing member for bearing over an external surface of the

blood vessel, and an internal bearing member for bearing against an inner surface of the blood vessel, where at least said internal bearing member is manipulable between a constricted position in which it is essentially coextensive with the wall-engaging portion and an expanded position in which it engages the inner surface of the blood vessel.

The device according to the present invention may assume many variations as will be disclosed hereinafter, all of which comprises a common principle component element namely, a manipulable internal bearing member and which are deployed into their operative, expanded position over the guide tube. The internal bearing member is expanded into its anchoring position within the vessel by means of a manipulating member which is in the form of a manipulating sleeve slidable over the guide tube or by deformation of a collapsing member, e.g. by pulling.

According to some embodiments of the invention, the internal bearing member spontaneously displaces into its anchoring state upon removal of the guide tube wherein the sealing portion spontaneously seals.

However, according to another aspect of the present invention there is provided a sealing device for sealing a puncture in a blood vessel, said device being slidingly receivable over a guide tube and comprising a sealing portion, a wall-engaging portion extending between an external bearing member for bearing over an external surface of the blood vessel, and an internal bearing member for bearing against an inner surface of the blood vessel, where said internal bearing member is a rib extending along a helical path. A device according to this aspect differs from devices according to the previous aspect in that the internal bearing member is fixed rather than being manipulable.

By a further aspect of the invention, there is provided a method for sealing a puncture in a blood vessel, the method comprising the following steps:

(a) obtaining a sealing assembly comprising a sealing device slidable over a guide tube and being axially displaceable over the guide tube by a manipulating member; said sealing device having a sealing body portion and a wall-engaging portion extending between an external bearing

member for bearing over an external surface of the blood vessel, and an internal bearing member for bearing against an inner surface of the blood vessel;

(b) mounting the sealing assembly over the guide tube;

(c) introducing the sealing assembly into the puncture site;

(d) displacing the sealing device over the guide tube by the manipulating member so as to introduce the wall-engaging portion through the puncture of the blood vessel;

(e) deploying the sealing device into a position in which the internal bearing member bears against an inner surface of the blood vessel; and

(f) removing the guide tube and allowing a sealing member of the device to assume a sealing position.

BRIEF DESCRIPTION OF THE DRAWINGS

For better understanding the invention and to see how it may be carried out in practice, reference is now being made to the accompanying drawings illustrating several embodiments in accordance with the present invention, in which:

Figs. 1A-1E are top isometric, bottom isometric, bottom, side and sectional views of a device in accordance with a first embodiment of the present invention, in an expanded position, removed from the guiding tube;

Figs. 2A and **2B** illustrate a perspective and a bottom view of the device seen in Figs. 1, in a retracted position mounted on a guide tube;

Figs. 3A and **3B** illustrate a sealing device in accordance with a second aspect of the invention in a deploying state and in operative, sealing state, respectively;

Fig. 4A is an isometric view of a sealing device in accordance with another embodiment of the present invention, mounted over a guide tube, in its constricted position;

Fig. 4B illustrates the device of Fig. 4A in a partially expanded position;

Fig. 4C illustrates the device of Figs. 4A and 4B in a sealing state engaged with a blood vessel in a sealing state;

Fig. 5A is a perspective view of a sealing device in accordance with still another embodiment of the present invention, the device illustrated in its constricted position;

Figs. 5B-5G are different views of a wall engaging portion and an internal bearing member of the device seen in Fig. 5A, in constricted and expanded positions;

Fig. 6A is an isometric view of device according to the present invention fitted with a wall engaging portion and an internal bearing member in accordance with a further embodiment, in a constricted position, mounted over a guide tube; and

Fig. 6B illustrates the device of Fig. 6A in its expanded, operative position.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

Attention is first directed to Figs. 1 and 2 of the drawings illustrating a first embodiment of a sealing device in accordance with the present invention generally designated **20**. The device has a generally tubular shape and has a fore end **22** and a distal end **24**. An intermediate, wall-engaging portion **26** is essentially cylindrical and has an inner diameter slidable over a guide tube (introducer sheath) **30** seen in Figs. 2A and 2B of the type which is used in different medical procedures.

Fixedly attached to the wall-engaging portion **26** there is a housing **32** accommodating a resilient membrane **34** pre-slotted to allow accommodation of the guide tube **30** as in Figs. 2A and 2B. Membrane **34** is normally closed, i.e. when not receiving a guide tube through the opening, it assumes a sealed state. A support ring **36** (Figs. 1A and 1E) is provided adjacent the fore end **22** of the device, formed with an aperture coaxial with the central cavity of the device extending through the wall-engaging portion **26**.

In the present example wall-engaging portion **26** is formed of a metallic material such as, for example, Nitinol or so-called medical type stainless steel,

whereas the housing **32** is composed of various elastomeric and plastic materials. However, a person versed in the art will appreciate that other combinations are possible. For example, the device may be partially or entirely made of bio-degradable (bio-absorbable) materials.

An annular shoulder **38** of housing **32** constitutes an external bearing surface which in use bears against an external surface **41** of the blood vessel as schematically illustrated in Fig. 1D.

Integrally formed with the wall-engaging portion **26** there is a pair of internal bearing arms **42** in the form of springy arcuate arms, each having one free end. The arrangement is such that the two arms are axially staggered whereby when they are retracted so as to coincide with the outer diameter of wall-engaging portion **26** they do not interfere with one another. The arrangement is further such that in their retracted position (Figs. 2A and 2B) they each extend over a circular portion larger than 180°C whereby when the guide tube **30** extends through the device **20** each arm embraces a portion of the tube **30** and is prevented from spontaneously displacing into the expanded position of Figs. 1A–1E, unless the tube is withdrawn.

An upper surface **46** of each of the internal bearing members **42** is adapted for bearing against an inner wall **48** of the blood vessel as illustrated in Fig. 1D.

Deployment of the device **20** into sealing engagement within a puncture formed in a blood vessel is carried out by introducing the guide tube **30** through the puncture (it is presumed that many medical procedures require the use of the guide tube and thus, the guide tube is already in position). In this case, the sealing device **20** is slidably displaced along the guide tube **30** towards the blood vessel and with the aid of a manipulating member in the form of tube **50** (Fig. 2A), which has a diameter larger than the diameter of the aperture formed in support ring **36**, and upon sliding the manipulating member **50** in direction of arrow **52** it entails displacement of the device **20** into the aperture at the blood vessel. Then, upon withdrawal of the guide tube **30** the internal bearing members **42** deform into their

wall-engaging position and the sealing diaphragm **34** spontaneously seals as the tube is withdrawn.

Further attention is now directed to Figs. 3A and 3B illustrating a device in accordance with a second aspect of the present invention. The device generally designated **60** has a generally tubular shape and comprises a fore end **62** with an opening **64** fitted for slidably receiving a guide tube **66**. Fitted adjacent the fore end **62** there is a sealing member **68**, similar to the arrangement disclosed in connection with the previous embodiment of Figs. 1 and 2.

The housing **70** of the device is formed with a neck portion **72** constituting an external bearing member for anchoring against an outer wall **74** of the blood vessel. An essentially cylindric portion **76** constitutes a wall-engaging portion which in the operative position of Fig. 3B occupies the puncture of the blood vessel. A bottom end of the device is formed with a rib **80** extending along a helical path, with an upper coil **82** of which constitutes an internal bearing member which in use bear against an internal wall **75** of the blood vessel, as seen in Fig. 3B.

The device **60** is deployed into its operative position over the guide tube **66** (Fig. 3A) and upon encountering the outer surface **74** of the blood vessel it is further inserted in a screw-type motion until the external bearing member **72** bears against the outer surface **74** of the blood vessel, entailing rib **82** to bear against inner wall **75**, anchoring the device in place. At this situation the guide tube **66** may be removed, allowing the diaphragm **68** to spontaneously deform into its sealed position as in Fig. 3B.

Figs. 4A-4C illustrate a sealing device **90** in accordance with still another embodiment of the present invention. The device is generally formed of a mesh of pre-stressed material, e.g. woven metal mesh or woven plastic material and has a fore end **92** and a bottom end **94**, pre-stressed to rotate in opposed directions illustrated by arrows **96** and **98** in Fig. 4B, thereby urging the device to rotate about a longitudinal axis thereof and displace into a collapsed state wherein the diameter of the device increases at its respective ends but shrinks to seal the internal bore thereof at a central portion. This arrangement is at times referred to as an *"Iris*

valve". Whilst the device may be made of a tight mesh material, it may be coated with a suitable material or embedded there within. The device may also be made of woven material with or without elastomeric coating.

The device **90** is initially mounted over a guide tube **96** as shown in Fig. 4A. In this position the device retains an essentially cylindric position. However, upon withdrawal of the guide tube **96** the device **90** tends to spontaneously deform into the position of Fig. 4C, owing to its pre-stressed structure. In this position there is formed an external bearing surface **98** and an internal bearing surface **100** (corresponding with ends **92** and **94** of the device), as illustrated in Fig. 4C, with an intermediate central portion **102** wound about itself and serving as a sealing member and as a wall-engaging portion. In this position the external bearing member **98** bears against outer wall surface **106** of the blood vessel with internal bearing member **100** bearing against inner wall surface **108** of the blood vessel, thus anchoring the device in place within the puncture **110**.

It will be appreciated that in addition to the above disclosed arrangement, there may be provided a resilient sealing member, e.g. of the type disclosed in the previous embodiments.

Attention is now directed to Figs. 5A-5G illustrating a further device in accordance with the present invention generally designated **120**, seen in a general perspective view in Fig. 5A. The device comprises a housing **122** which is principally similar to the housing **32** in the first embodiment illustrated in Figs. 1 and 2. Housing **122** comprises a support ring **124**, a pre-slotted diaphragm-like sealing member **126** and an annular shoulder **128** constituting an external bearing surface. Fitted to housing **122** there is a wall-engaging portion **130** which is separately illustrated in Figs. 5B-5G. As explained in connection with the first embodiment, the internal diameter of the wall-engaging portion **130** is designed for sliding over a guide tube (not shown).

Formed at a bottom end of wall-engaging portion **130** there are two internal bearing members **134** each formed of a pre-stressed wire having at least three parallel looped portions **136, 138** and **140** (most clearly illustrated in the side view

of Fig. 5C). Each of the bearing members **134** has two leg portions **142** fixed to or integral with the wall-engaging portion **130**. The arrangement is such that at the constricted position (Figs. 5A-5C) the looped portions **136, 138** and **140** extend essentially parallel to a longitudinal axis of the device and thus the device is readily slidable over the guide tube (not shown). However, upon withdrawal of the guide tube, the internal bearing members **134** spontaneously snap into their expanded position as in Figs. 5D-5F, with the longer looped portions **138** laterally projecting outwardly. In the expanded position the long looped portions **138** bear against the inner surface of the blood vessel (not shown). As can be seen in particular in Fig. 5E, at the expanded position the looped portions **138** are upwardly inclined so as to improve anchoring within the vessel.

Deploying the device **120** into its operative position is done as in the description referring to the first embodiment whereupon displacement of the device over the guide tube (not shown) into the puncture of the blood vessel and then withdrawal of the guide tube entails spontaneous expansion of the internal bearing member and sealing of the seal member **126**.

Figs. 6A and 6B illustrate still a further embodiment of the present invention generally designated **150** which in Fig. 6A is illustrated in its retracted position and in Fig. 6B in its expanded, operative position. The sealing portion generally designated **152** is similar to that disclosed in connection with the previous embodiments and the rear is directed to the relevant passages hereinabove. An annular shoulder **154** of the sealing portion **152** constitutes the external bearing surface.

Fitted to the housing of sealing member **152** there is a wall engaging portion **158** which is tubular portion adapted for fit sliding over an introducing sheath **160** (seen only in Fig. 6A). The tubular member **158** is formed with a plurality of axial slots **164** wherein between two consecutive slots **164** there is a deformable internal wall fixing members **170**, each formed with an integral radial fold-line **174**.

A pair of deploying cords **178** extend through the tubular member **158** and are attached at **180** to a lowermost portion **182** of the tubular member **158**.

The arrangement is such that at an initial state the internal engaging members **170** are coaxial with other portions of the tubular member **158** and upon pulling cords **178** in the axle direction illustrated by arrows **186**, the internal engaging member collapses outwardly as illustrated in Fig. 6B, thereby constituting the internal anchor for bearing against an internal surface of the blood vessel.

Whilst some embodiments have been described and illustrated with reference to some drawings, the artisan will appreciate that many variations are possible which do not depart from the general scope of the invention, *mutatis, mutandis*. For example, different materials may be used for obtaining different mechanical properties of different components of the device, e.g. pre-stressing, durability, etc. Furthermore, at least portions of the devices may be coated or made of anti-coagulant material as known *per se*.

CLAIMS:

1. A sealing device for sealing a puncture in a blood vessel, said device being slidingly receivable over a guide tube and comprising a sealing portion, a wall-engaging portion extending between an external bearing member for bearing over an external surface of the blood vessel, and an internal bearing member for bearing against an inner surface of the blood vessel, where at least said internal bearing member is manipulable between a constricted position in which it is essentially coextensive with the wall-engaging portion and an expanded position in which it engages the inner surface of the blood vessel.

2. A sealing device according to Claim 1, wherein the internal bearing member spontaneously manipulable between the constricted position and the expanded position, upon withdrawal of the guide tube.

3. A device according to Claim 2, wherein the sealing portion spontaneously seals upon withdrawal of the guide tube.

4. A sealing device according to Claim 1,wherein the diameter of the external bearing member exceeds the boundaries of the puncture.

5. A sealing device according to Claim 1, wherein the guide tube is an introducer sheath used in a medical procedure.

6. A sealing device according to Claim 5, wherein the device is propelled off the guide tube by a manipulating member slidable thereover.

7. A sealing device according to Claim 1, wherein the wall-engaging portion has a cylindrical cross-section.

8. A device according to Claim 1, wherein it is axially displaceable over the guide tube by a manipulating tube slidable over the guide tube.

9. A device according to Claim 8, wherein the manipulating device is detachably articulated to the sealing device.

10. A device according to Claim 1, wherein the internal bearing member comprises at least a pair of arms, each having at least a laterally expandable engaging portion.

11. A device according to Claim 10, wherein the engaging arms are arcuated arms, each having a first end attached to the wall-engaging portion, and a second, free end; wherein at the constructed position a portion of the arm embraces the guide tube.

12. A device according to Claim 11, wherein at the constricted position the arcuated arms extend over an arc greater then 180°.

13. A device according to Claim 1, wherein one or both of the internal bearing member and the external bearing member comprises at least two pre-stressed wire formed with at least three parallel looped portions having two leg portions fixed to the wall engaging portion in parallel relation, wherein at the constricted position thereof the leg portions and the looped portions extend parallel with respect to the wall-engaging portion, and at the expanded position the looped portions radially project from the wall engaging portion.

14. A device according to Claim 13, wherein the looped portions comprise a long loop extending between two shorter loops; the axial length of the shorter loops being less then the radius of the wall engaging portion, and the axial length of the longer loop is about double the length of the shorter loops.

15. A sealing device for sealing a puncture in a blood vessel, said device being slidingly receivable over a guide tube and comprising a sealing portion, a wall-engaging portion extending between an external bearing member for bearing over an external surface of the blood vessel, and an internal bearing member for bearing against an inner surface of the blood vessel, where said internal bearing member is a rib extending along a helical path.

16. A device according to Claim 1, wherein the external bearing member is an annular shoulder.

17. A device according to Claim 1, wherein the internal bearing member is formed by forming at least two flaps, each defined between a pair of axially extending slots, said flaps being collapsible along about lateral fold lines.

18. A device according to Claim 17, wherein the internal bearing member is deployed into the expanded position by axially retracting a distal end of the device.

19. A device according to Claim 1, comprising a coiled body pre-stressed so that a top end and a bottom end are urged to twist in opposed directions about a longitudinal axis thereof; said top and bottom end serve as the internal bearing member and external bearing member, respectively; said device having a constricted position in which it retains an essentially cylindrical position, and an expanded, twisted position in which it's the internal bearing member and the external bearing member radially project with respect to the wall-engaging portion.

20. A device according to Claim 19, wherein when mounted over the guide tube it obtains a cylindrical position and when deployed from the guide member it spontaneously retains its expanded position, having the general shape of two inverted cones.

21. A device according to Claim 17, wherein it is normally urged to axially constrict.

22. A device according to Claim 1, wherein the sealing portion comprises a slotted aperture accommodating the guide tube and adapted for spontaneously sealing upon removing the guide tube.

23. A sealing device according to Claim 1, wherein the axial length of the wall-engaging portion is in the range of about 0.5-2.5 mm.

24. A sealing device according to Claim 1, wherein the diameter of the wall-engaging portion is in the range of about 1-7 mm.

25. A method for sealing a puncture in a blood vessel, the method comprising the following steps:

(a) obtaining a sealing assembly comprising a sealing device slideable over a guide tube and being axially displaceable over the guide tube by a manipulating member; said sealing device having a sealing portion and a wall-engaging portion extending between an external bearing member for bearing over an external surface of the blood vessel, and an internal bearing member for bearing against an inner surface of the blood vessel;

(b) introducing the sealing assembly into the puncture site;

(c) displacing the sealing device over the guide tube by the manipulating member so as to introduce the wall-engaging portion through the puncture of the blood vessel;

(d) deploying the sealing device into an expanded position in which internal bearing member of the sealing device bear against an inner surface of the blood vessel; and

(e) removing the guide tube and allowing the sealing member to assume a sealing position.

26. A method according to Claim 25, wherein the manipulating member is detachably articulated to the sealing device and wherein prior to step (e) the manipulating member is detached from the sealing member.

27. A method according to claim 26, wherein prior to step (c) there is a further step of mounting the sealing assembly over the guide tube.

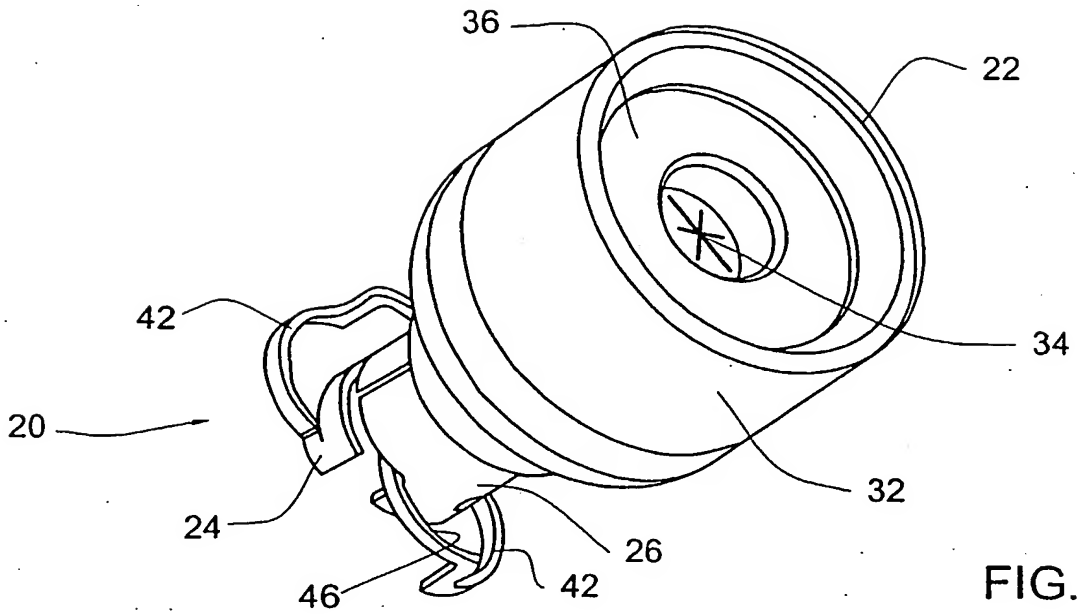


FIG. 1A

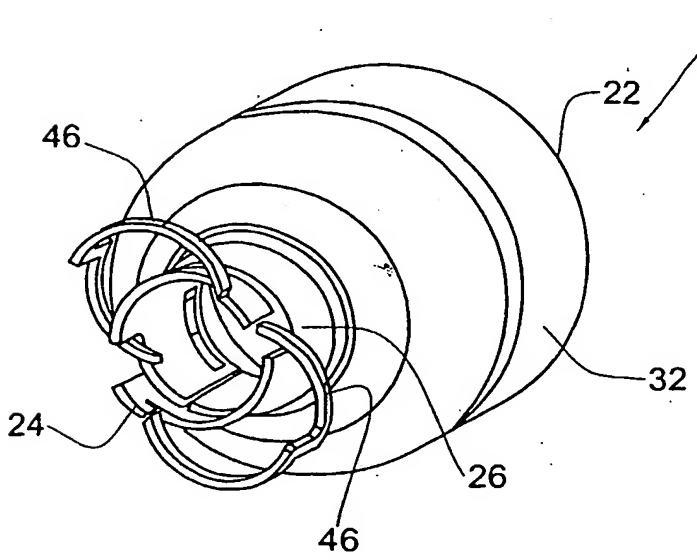


FIG. 1B

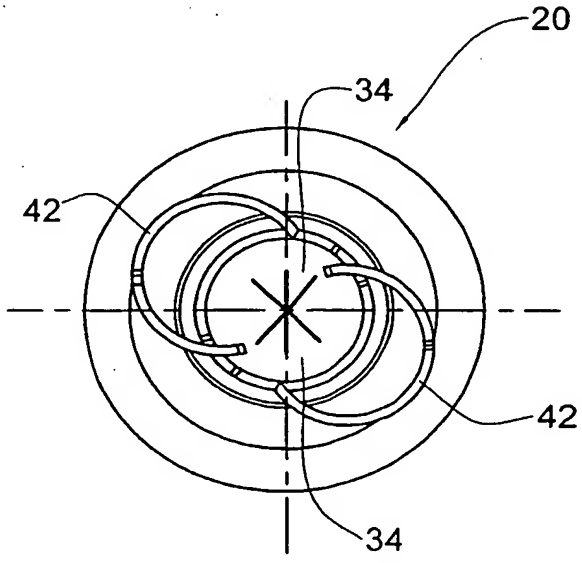


FIG. 1C

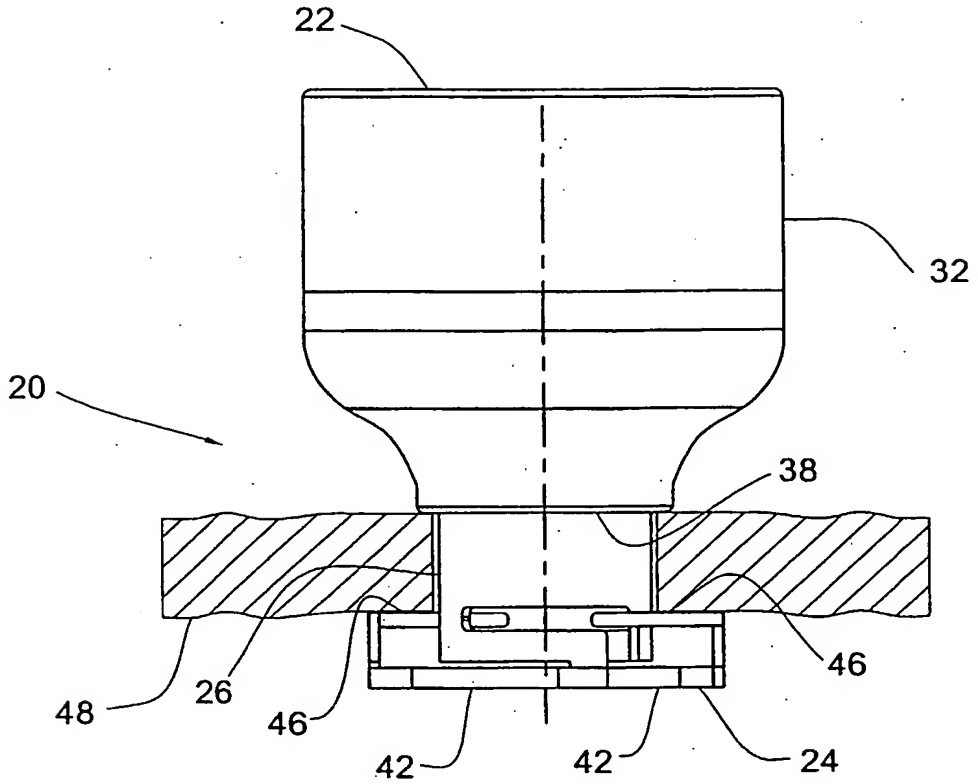


FIG. 1D

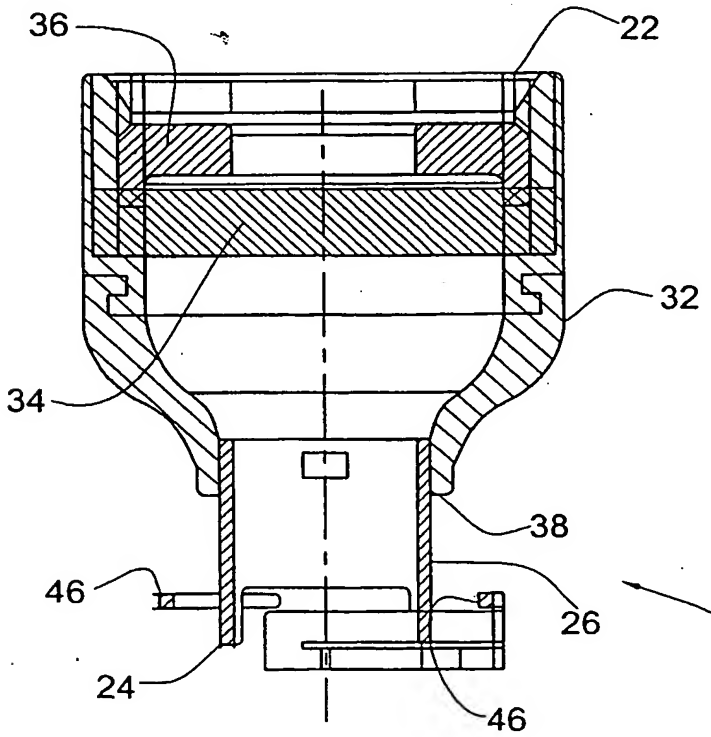


FIG. 1E

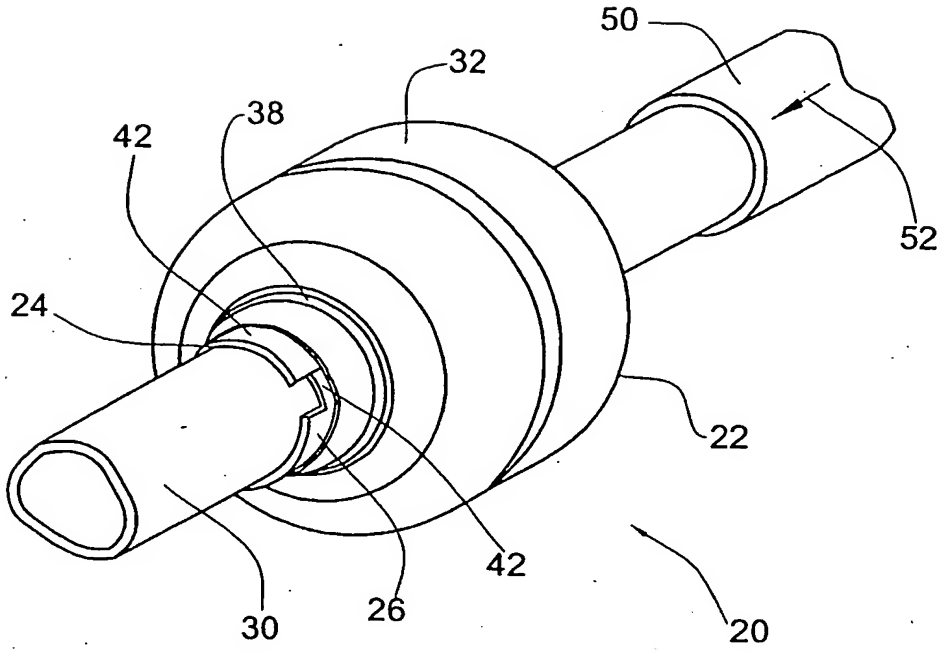


FIG. 2A

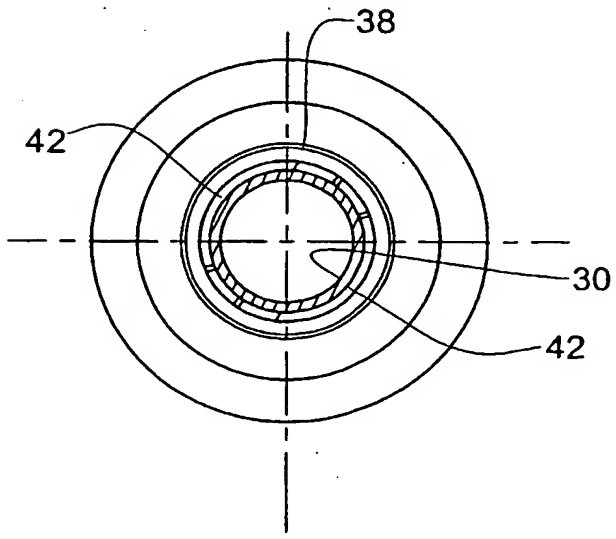


FIG. 2B

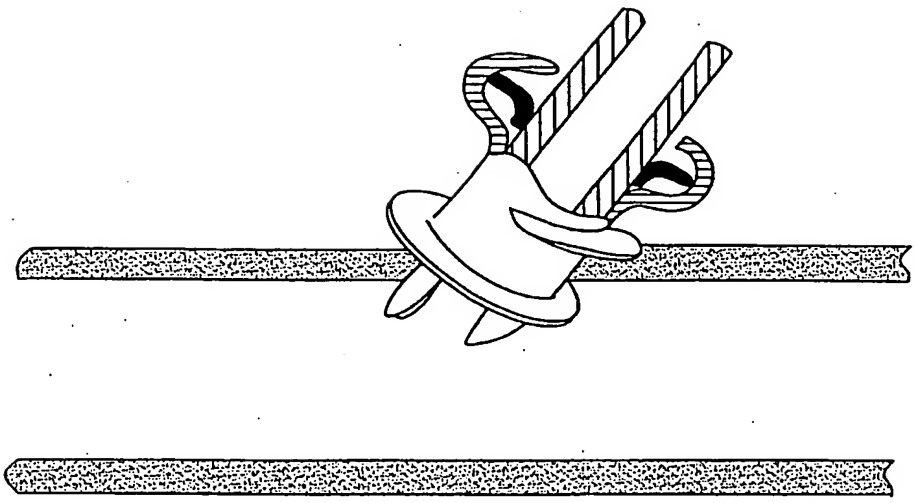


FIG. 3A

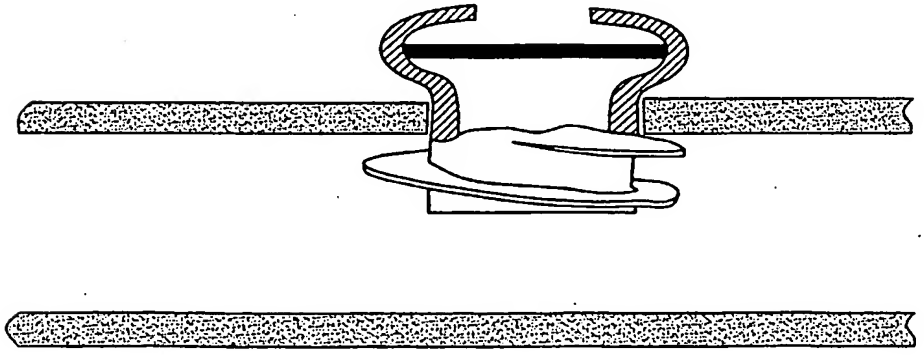


FIG. 3B

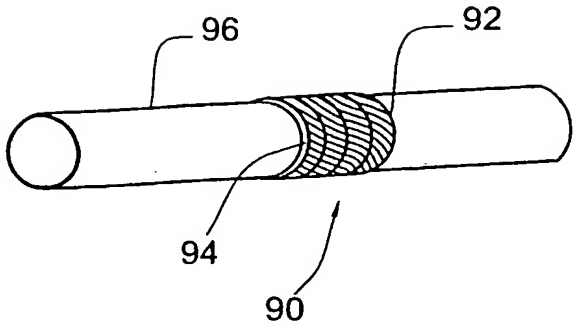


FIG. 4A

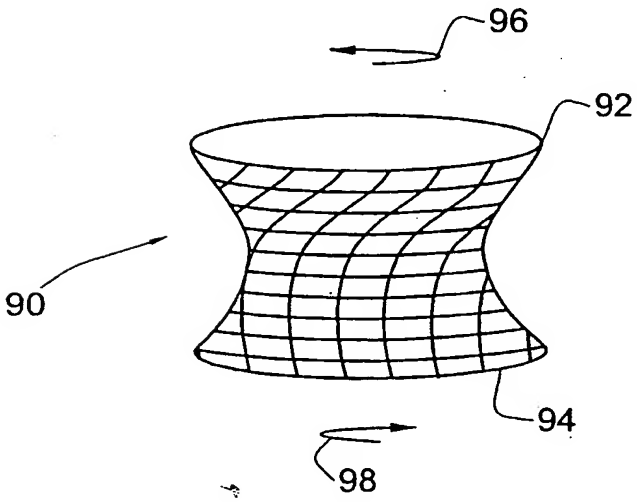


FIG. 4B

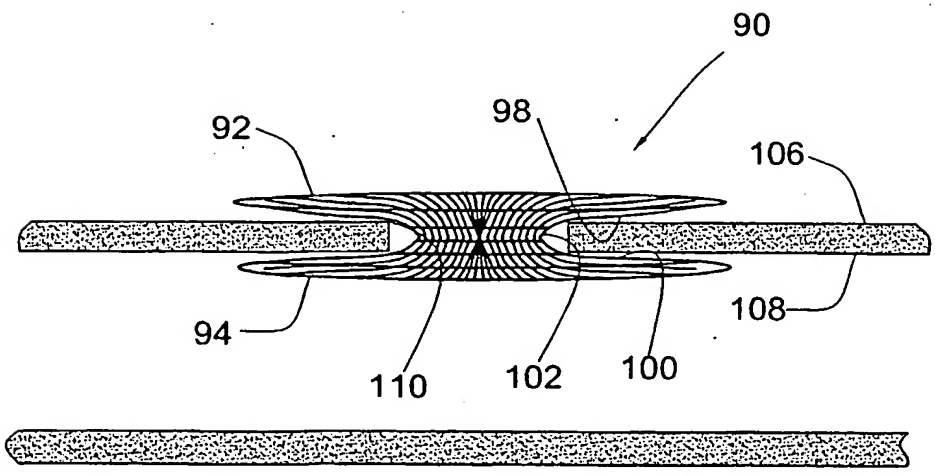


FIG. 4C

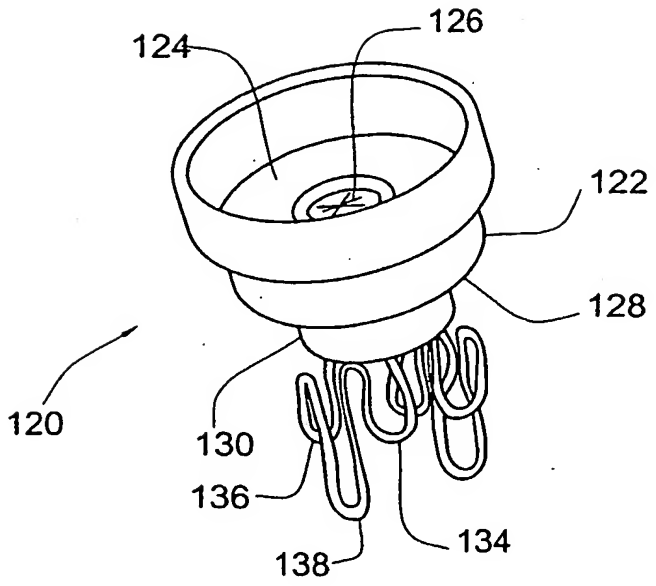
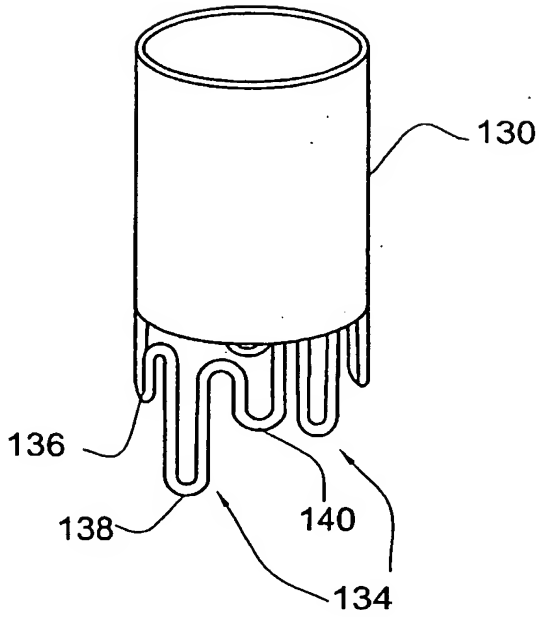


FIG. 5A

FIG. 5B



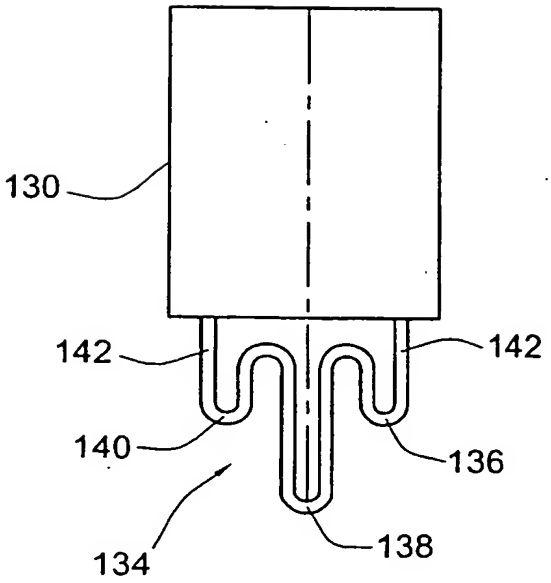


FIG. 5C

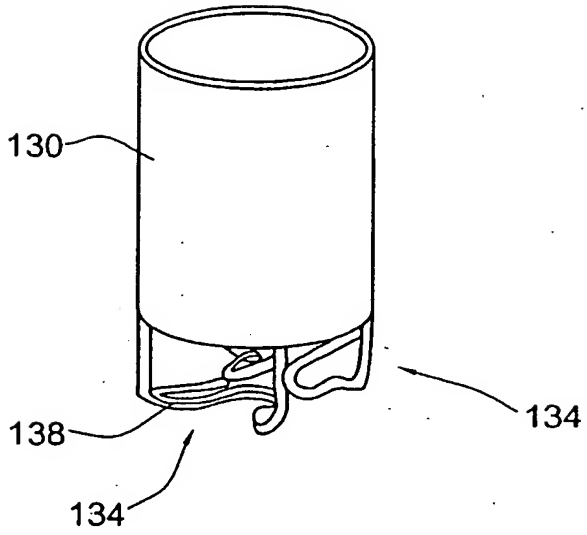


FIG. 5D

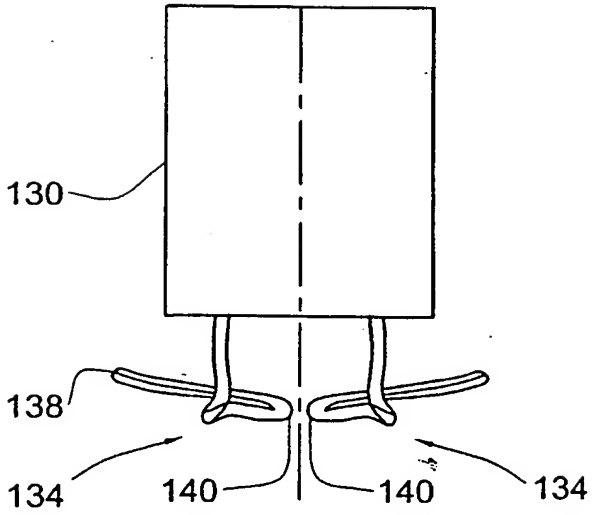


FIG. 5E

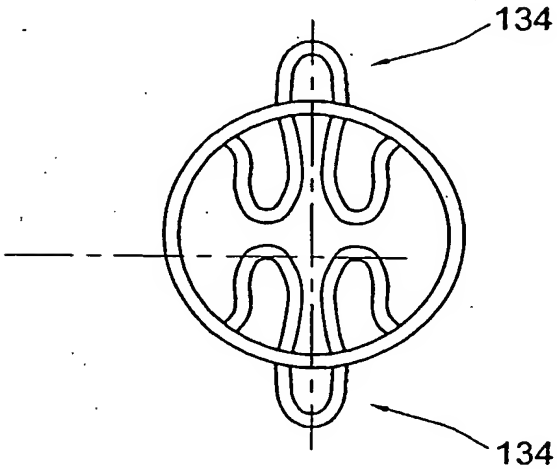


FIG. 5F

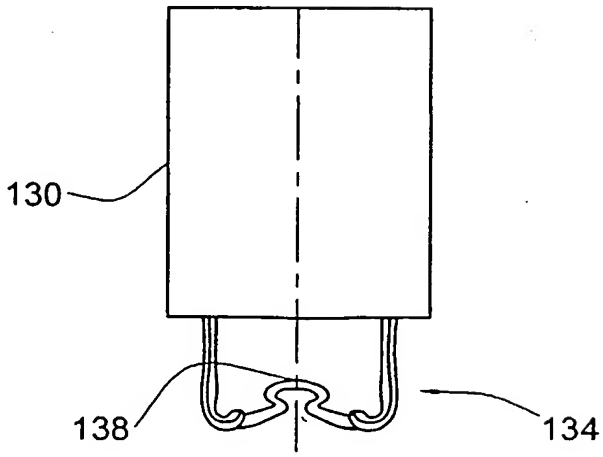


FIG. 5G

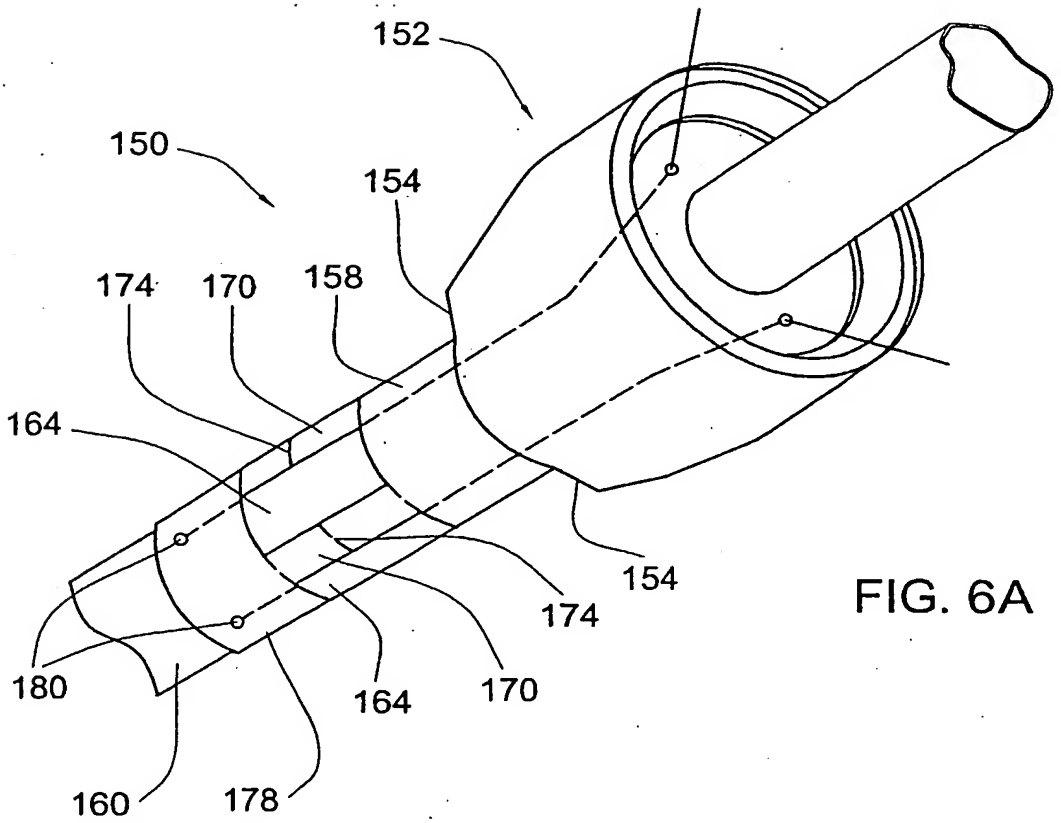

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FIG. 6A

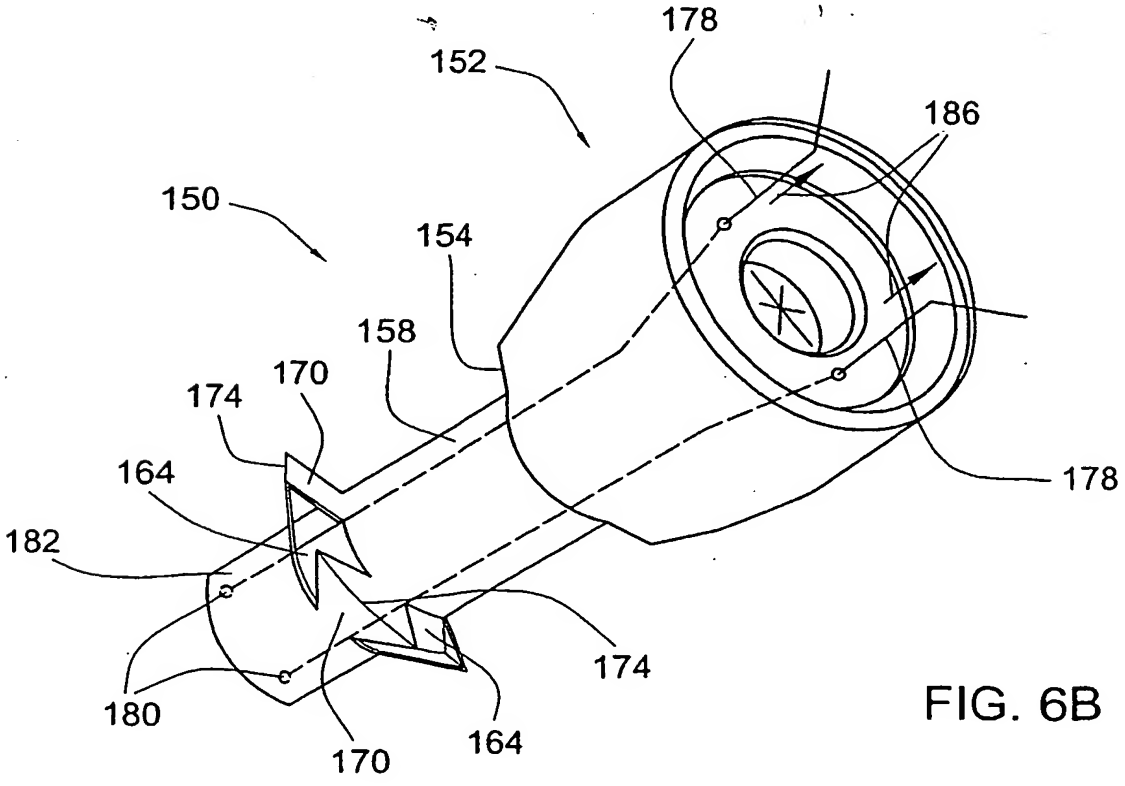
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FIG. 6B

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(71) Applicant *(for all designated States except US)*: VASCU-LAB LTD. [IL/IL]; 21 King Shaul Boulevard, 64367 Tel Aviv (IL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: BASH, Assaf [IL/IL]; Haseora 1, 37808 Givat Ada (IL). BAR-OR, Jonathan [IL/IL]; Kibbutz Degania A, 15120 Jordan Valley (IL). SHACHAR, Rotem [IL/IL]; Kibbutz Metzer, 38820 Mobile Post Hefer (IL). BEN DAVID, Shlomo [IL/IL]; 19 Yehuda Hanasi Street, 69206 Tel Aviv (IL).

(74) Agent: REINHOLD COHN AND PARTNERS; P.O.Box 4060, 61040 Tel Aviv (IL).

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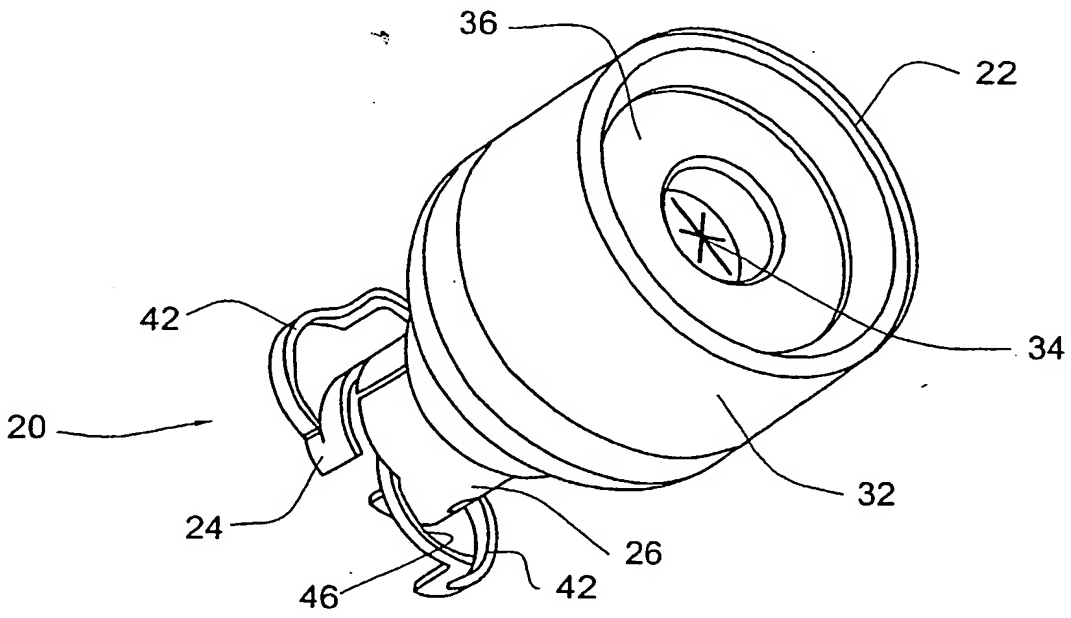
Published:
— *with international search report*

[Continued on next page]

(54) Title: DEVICE AND METHOD FOR SEALING A PUNCTURE IN A BLOOD VESSEL



(57) Abstract: A sealing device for sealing a puncture in a blood vessel, the device being slidingly receivable over a guide tube and comprising a sealing portion, a wall-engaging portion extending between an external bearing member for bearing over an external surface of the blood vessel, and an internal bearing member for bearing against an inner surface of the blood vessel. At least the internal bearing member is manipulable between a constricted position in which it is essentially coextensive with the wall-engaging portion and an expanded position in which it engages the inner surface of the blood vessel.

WO 02/032320 A3

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
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International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Date of the actual completion of the international search	Date of mailing of the international search report
21 May 2002	06/06/2002

Name and mailing address of the ISA	Authorized officer
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